PepGen Reports Third Quarter 2023 Financial Results and Recent Corporate Developments

November 8, 2023

- Continuing to open CONNECT1-EDO51 trial sites in Canada -

- Opening of FREEDOM-DM1 trial sites underway in the U.S. and Canada -

- Ended third quarter 2023 with cash and cash equivalents of $129.5 million; cash runway expected into 2025 -

BOSTON, Nov. 08, 2023 (GLOBE NEWSWIRE) -- PepGen Inc. (Nasdaq: PEPG), a clinical-stage biotechnology company advancing the next generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases, today reported financial results for the third quarter ended September 30, 2023 and highlighted recent corporate developments.

“We made significant progress across our pipeline of Enhanced Delivery Oligonucleotide (EDO) candidate therapeutics in the third quarter of 2023, including positive news from regulatory authorities that enable the launch of our FREEDOM-DM1 study in the U.S. and Canada,” said James McArthur, Ph.D., President and CEO of PepGen. “We were pleased to have been cleared by the U.S. Food and Drug Administration (FDA) to conduct the FREEDOM-DM1 study at target dose levels, 5 mg/kg, 10 mg/kg, and 20 mg/kg, that we believe could benefit patients in a clinically meaningful way. In addition, we were happy to report that the FDA granted Orphan Drug Designation to PGN-EDODM1 for the treatment of myotonic dystrophy type 1 (DM1).”

Dr. McArthur added, “We also remain focused on continuing to advance our CONNECT1-EDO51 study evaluating PGN-EDO51 in Duchenne muscular dystrophy, and look forward to reporting dystrophin production, exon skipping and safety data following 4 monthly doses of PGN-EDO51 in mid-2024.”

Recent Corporate Highlights

- **Clinical hold lifted by FDA for FREEDOM-DM1:** In October 2023, PepGen announced that the FDA lifted the clinical hold on its Investigational New Drug application and cleared the Company to initiate the FREEDOM-DM1 Phase 1 study of PGN-EDODM1 in patients with DM1 in the U.S. The lifting of the clinical hold enables PepGen to launch the FREEDOM-DM1 study in the U.S. with target dose levels of 5 mg/kg, 10 mg/kg and 20 mg/kg.
- **Orphan Drug Designation granted to PGN-EDODM1:** In September 2023, the FDA granted Orphan Drug Designation to PGN-EDODM1 for the treatment of DM1.
- **Clearance of FREEDOM-DM1 CTA by Health Canada:** In September 2023, the Company received a No Objection Letter from Health Canada for its Clinical Trial Application to initiate the FREEDOM-DM1 Phase 1 study of PGN-EDODM1 in patients with DM1 in Canada at target dose levels, 5 mg/kg, 10 mg/kg, and 20 mg/kg. PepGen expects to report initial results from this study in 2024.
- **EDO Platform and PGN-EDODM1 preclinical data presented at medical conferences:** PepGen presented preclinical non-human primate (NHP) data supporting its proprietary EDO platform at the 6th Ottawa International Conference on Neuromuscular Disease and Biology and preclinical murine data for PGN-EDODM1 at the 2023 Myotonic Dystrophy Foundation Annual Conference. The Company reported that its EDO platform drove 25-fold higher level of oligonucleotide delivery to myotube nuclei compared to “naked” oligonucleotide and that its EDO technology enabled delivery of therapeutic oligonucleotide to 72% of muscle nuclei in non-human primates. In addition, the Company reported that PGN-EDODM1 corrected 99% of mis-splicing and reversed 99% of myotonia following multiple doses in a DM1 murine model.

Anticipated Upcoming Milestones

- **PGN-EDO51:** PepGen anticipates dosing patients in CONNECT1-EDO51, an open-label,

multiple ascending dose (MAD) Phase 2 study in Canada, in the fourth quarter of 2023 or early in the first quarter of 2024 and initiating CONNECT2-EDO51, a Phase 2 multinational, randomized, double-blind, placebo-controlled MAD study, in the first quarter of 2024. The Company continues to anticipate proof-of-concept data, including exon skipping and dystrophin data, as well as safety data, at the 5 mg/kg PGN-EDO51 dose level for exon 51-skipping amenable DMD patients in the CONNECT1-EDO51 clinical study in mid-2024.

Financial Results for the Three Months Ended September 30, 2023

- **Cash and cash equivalents** were $129.5 million as of September 30, 2023, which is anticipated to fund currently planned operations into 2025.
- **Research and Development expenses** were $20.5 million for the three months ended September 30, 2023, compared to $16.0 million for the same period in 2022.
- **General and Administrative expenses** were $4.2 million for the three months ended September 30, 2023, compared to $3.6 million for the same period in 2022.
- **Net loss** was $23.3 million for the three months ended September 30, 2023, compared to $18.6 million for the same period in 2022. PepGen had approximately 23.8 million shares outstanding on September 30, 2023.

About PepGen

PepGen Inc. is a clinical-stage biotechnology company advancing the next-generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases. PepGen's Enhanced Delivery Oligonucleotide, or EDO, platform is founded on over a decade of research and development and leverages cell-penetrating peptides to improve the uptake and activity of conjugated oligonucleotide therapeutics. Using these EDO peptides, we are generating a pipeline of oligonucleotide therapeutic candidates that are designed to target the root cause of serious diseases.

About PGN-EDODM1

PGN-EDODM1 is an investigational candidate designed to deliver a peptide-conjugated antisense oligonucleotide (ASO) to restore cellular function. DM1 is caused by an expansion of CUG repeats that form hairpin loops in the DMPK RNA, resulting in sequestration of the MBNL1 protein, a key RNA processing factor. The sequestration of MBNL1 results in downstream mis-splicing events and aberrant expression of many proteins that play a critical role in muscle and other systemic functions (e.g. endocrine, gastrointestinal, central nervous system). By specifically blocking the toxic CUG repeats, the goal of PGN-EDODM1 is to liberate MBNL1 protein and to restore functional downstream splicing and muscle and other systemic functions.

About Myotonic Dystrophy Type 1 (DM1)

Myotonic dystrophy type 1, or DM1 (also known as Steinert's disease), is a progressively disabling, life-shortening genetic disorder. DM1 is the most prevalent form of the disease and generally the most severe. DM1 affects an estimated 40,000 people in the U.S., and 70,000 in the EU. The average life expectancy for people living with DM1 is 45-60 years old. People living with DM1 typically present with myotonia (stiff or contracted muscles), muscle weakness, and cardiac and respiratory abnormalities. Many people living with DM1 also experience excessive daytime sleepiness, fatigue, and issues with gastrointestinal or cognitive dysfunction that significantly affect their quality of life.

About PGN-EDO51

PGN-EDO51, PepGen's lead clinical candidate for the treatment of Duchenne muscular dystrophy (DMD), utilizes the Company's proprietary Enhanced Delivery Oligonucleotide (EDO) technology to deliver a therapeutic oligonucleotide that is designed to target the root cause of this devastating disease. PGN-EDO51 is designed to skip exon 51 of the dystrophin transcript, an established therapeutic target for approximately 13% of DMD patients, thereby aiming to restore the open reading frame and enabling the production of a truncated, yet functional dystrophin protein. In preclinical studies, PepGen observed that treatment of non-human primates with PGN-EDO51 resulted in greater levels of exon-skipping when compared in head-to-head studies against a molecule that we believe is structurally equivalent to the most clinically-advanced peptide-conjugated oligonucleotide therapeutic candidate, which could translate to higher levels of dystrophin production in patients. PGN-EDO51 also exhibited the highest level of exon 51 skipping in primate skeletal muscles, including the diaphragm, reported for any approved therapeutic or known development candidate, based on cross-trial comparisons of publicly available data with preclinical PGN-EDO51 data. In humans, in a single ascending dose study, PGN-EDO51 also exhibited the 20-fold higher exon 51 skipping than naked oligo following a single dose, based on cross-trial comparisons of publicly available data with clinical PGN-EDO51 data.

About Duchenne Muscular Dystrophy (DMD)

Duchenne muscular dystrophy (DMD) is an X-linked recessive muscle-wasting disease that predominantly affects males. This debilitating disease is caused by genetic mutations in the gene encoding dystrophin, a protein critical for healthy muscle function, and is one of the most prevalent rare genetic diseases, with an incidence rate of approximately one in every 3,500 to 5,000 male births. DMD is characterized by progressive muscle weakness, which leads to patients losing the ability to walk, a loss of upper body function, cardiac issues and difficulties breathing. DMD is invariably fatal by young adulthood. Despite significant advances in treatments for this devastating disease, current therapies are limited by poor delivery to muscle tissue and have yet to establish meaningful clinical benefit for DMD patients.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These

statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will,” and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding the therapeutic potential and safety profile of our product candidates including PGN-EDO51 and PGN-EDODM1, our technology, including our EDO platform, the design, initiation and conduct of clinical trials, including expected timelines, dose levels, regulatory interactions, including development pathway for our product candidates, and our financial resources and cash runway.

Any forward-looking statements in this press release are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to risks related to: delays or failure to successfully initiate or complete our ongoing and planned development activities for our product candidates, including PGN-EDO51 and PGN-EDODM1; our ability to enroll patients in our clinical trials; our interpretation of clinical and preclinical study results may be incorrect, or that we may not observe the levels of therapeutic activity in clinical testing that we anticipate based on prior clinical or preclinical results; our product candidates may not be safe and effective or otherwise demonstrate safety and efficacy in our clinical trials; adverse outcomes from our regulatory interactions, including delays in regulatory review, clearance to proceed or approval by regulatory authorities with respect to our programs, including clearance to commence planned clinical studies of our product candidates, including PGN-EDO51 and PGN-EDODM1, or other regulatory feedback requiring modifications to our development programs; changes in regulatory framework that are out of our control; unexpected increases in the expenses associated with our development activities or other events that adversely impact our financial resources and cash runway; and our dependence on third parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks concerning PepGen’s programs and operations are described in our most recent annual report on Form 10-K and quarterly report on Form 10-Q that are filed with the SEC. PepGen explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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Condensed Consolidated Statements of Operations
(unaudited, in thousands except share and per share amounts)

	Three Months Ended September 30,	
	2023	2022
Operating expenses:		
Research and development	$ 20,540	$ 15,964
General and administrative	4,240	3,590
Total operating expenses	$ 24,780	$ 19,554
Operating loss	$ (24,780)	$ (19,554)
Other income (expense)		
Interest income	1,578	943
Other income (expense), net	(88)	4
Total other income, net	1,490	947
Net loss before income tax	$ (23,290)	$ (18,607)
Income tax expense	—	—
Net loss	$ (23,290)	$ (18,607)
Net loss per share, basic and diluted	$ (0.98)	$ (0.79)
Weighted-average common shares outstanding, basic and diluted	23,790,430	23,562,395

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 129,538	$ 181,752
Prepaid expenses and other current assets	3,552	4,331
Total current assets	$ 133,090	$ 186,083
Property and equipment, net	$ 5,042	$ 3,335

Operating lease right-of-use asset	24,149	26,549
Other assets	1,990	1,473
Total assets	$ 164,271	$ 217,440
Liabilities, convertible preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,989	$ 1,362
Accrued expenses	13,984	11,913
Operating lease liability	2,982	5,553
Total current liabilities	$ 20,955	$ 18,828
Operating lease liability, net of current portion	17,451	18,981
Total liabilities	$ 38,406	$ 37,809
Commitments and contingencies		
Convertible preferred stock	$ —	$ —
Stockholders' equity (deficit)		
Common stock	$ 2	$ 2
Additional paid-in capital	287,907	282,566
Accumulated other comprehensive (loss) income	(57)	(81)
Accumulated deficit	(161,987)	(102,856)
Total stockholders' equity	$ 125,865	$ 179,631
Total liabilities, convertible preferred stock, and stockholders' equity	$ 164,271	$ 217,440